IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

JOANNA MCCOY, *et al.*,	*	**Case No.: 1:12-cv-01436-ELH/JMC**
Plaintiffs,	*	**Judge Ellen L. Hollander**
v.	*	
BIOMET ORTHOPEDICS, LLC, *ET AL.*	*	
Defendants.	*	

DEFENDANTS' MEMORANDUM OF LAW IN
SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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I. INTRODUCTION

Plaintiffs allege product liability claims[1] against Biomet[2] involving an artificial hip device (called the M2a Magnum) implanted in the right hip of Plaintiff Ms. McCoy[3] in December 2007. But their claims that alleged defects in the M2a Magnum caused Ms. McCoy's injuries and need for additional hip replacement surgeries (called hip revision surgeries) cannot survive summary judgment. Ms. McCoy's right hip was revised to address suboptimal placement of her acetabular cup and subsequent loosening complicated by a likely periprosthetic infection; not because of a product defect. Indeed, the undisputed facts show that none of Plaintiffs' claims have legal merit for several reasons.

First, Plaintiffs have no evidence that there was a manufacturing defect in Ms. McCoy's M2a Magnum implant. The Court should dismiss Plaintiffs' manufacturing-based claims as a matter of law.

Second, expert testimony is required in complex medical devices case such as this one. If the Court grants Biomet's contemporaneously filed motions to exclude and limit the opinions of Plaintiffs' case-specific medical experts, Jeffrey F. Shapiro, M.D., and Frank Ebert, M.D.,

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[1] Strict Product Liability (Count I); Negligence (Count II); Breach of Implied Warranties (Count III); Breach of Express Warranty (Count IV); Punitive Damages (Count IV); Loss of Consortium (Count VI). There is no Count V in Plaintiffs' First Amended Complaint.

[2] Defendants Biomet Orthopedics, LLC, Biomet Manufacturing LLC f/k/a Biomet Manufacturing Corp., Biomet U.S. Reconstruction, LLC, and Zimmer Biomet Holdings, Inc. are collectively referred to as "Defendants" or "Biomet." Zimmer Biomet Holdings, Inc. ("ZBH") should be dismissed from this case for the reasons set forth in Defendants' Motion for Summary Judgment and this supporting Memorandum and also for the reasons set forth in ZBH's pending Motion to Dismiss for Lack of Personal Jurisdiction, filed on February 21, 2019 (Doc. No. 46) which is incorporated herein by reference.

[3] Plaintiff Dr. JoAnna McCoy is a veterinarian. For purposes of clarity in this medical device case involving multiple physicians and surgeons, Biomet refers to Plaintiff Dr. JoAnna McCoy throughout its briefing as "Ms. McCoy."

Plaintiffs would not be able to prove medical causation – an essential element of all of Plaintiffs' claims, and all claims would fail accordingly.

Third, irrespective of whether the Court grants Biomet's motions to exclude, Plaintiffs' experts have failed to offer any opinions supporting a claim that the M2a Magnum had any specific defect that caused Plaintiff Joanna McCoy's alleged injuries. Plaintiffs' failure to present expert evidence establishing defect and causation leaves Biomet's experts' testimony that the M2a Magnum did not cause Plaintiffs' injuries unrebutted. Put simply, the only admissible expert evidence – Biomet's evidence – disproves Plaintiffs' case and establishes that the M2a Magnum did not cause Ms. McCoy's need for revision surgeries. Instead, Ms. McCoy's need for revision surgeries was related to patient and clinical factors, not the M2a Magnum device itself. Ms. McCoy's right M2a Magnum device needed to be revised due to the acetabular cup's suboptimal positioning and lack of porous ingrowth which led to its loosening and also due to likely periprosthetic infection within the right hip.

Fourth, Plaintiffs' warning claims fail by application of the learned intermediary doctrine and the law of proximate causation. The M2a Magnum's warnings are adequate as a matter of law, and Plaintiffs cannot show that a different warning would have caused Ms. McCoy's implanting surgeon Dr. Marc Brassard to make a different decision about device selection.

Fifth, Plaintiffs' general negligence claim fails because Maryland product liability law does not recognize free-standing negligence claims. Only three claims involving negligence are available to Plaintiffs – negligent design, manufacturing, and warning – and each claim fails here.

Sixth, Plaintiffs' warranty claims fail because they did not give Biomet notice and did not identify any descriptions or statements about the M2a Magnum that formed the basis for selecting the implant used in Ms. McCoy's right hip replacement surgery. Dr. Brassard testified he did not

select the M2a Magnum based on marketing materials or specific information from Biomet. Most significantly, Dr. Brassard denied that any statements from Biomet impacted his treatment decisions.

Seventh, Plaintiffs' request for punitive damages fails because their underlying product liability claims fail. Also, Plaintiffs' request for punitive damages is not supported by sufficient evidence, and they cannot otherwise meet the high standard for an award of punitive damages and prove actual malice.

Finally, Plaintiff Kenneth Burgwin's derivative loss of consortium claim necessarily fails because his spouse, Ms. McCoy, has no valid claims.

II. STATEMENT OF MATERIAL FACTS

A. Plaintiff Joanna McCoy's medical history and total right hip replacement surgery

Ms. McCoy has an extended history of orthopedic complaints, having fractured her right hip as a child. *See* Joanna McCoy Medical Records, at JHH 7, attached hereto as "**Exhibit A**." In 2002, Ms. McCoy sought treatment for tailbone pain. Ex. A, McCoy Records, at POA 21. X-Ray imaging revealed significant arthritis in both of her hips. *Id.* Starting in October 2006, Ms. McCoy sought treatment for persistent back and hip pain from various orthopedic surgeons. *See* Ex. A, McCoy Records, at POA 7, 12; UMOSM2 24, PRWOMRI 24-26. She was diagnosed with degenerative disc disease with lumbar radiculopathy. *See id.* Ms. McCoy started seeing orthopedic surgeon Dr. Marc Brassard in April 2007. Ex. A, McCoy Records, at TOSPB 5. Dr. Brassard observed she had continued significant hip, back, and sacroiliac joint pain in October 2007 and diagnosed her with bilateral hip arthritis and degenerative joint disease. Ex. A., McCoy records, at TOSPB 9. Dr. Brassard recommended a right hip replacement surgery as a way to alleviate her arthritic hip pain. *See* Ex. A, McCoy records, at TOSPB 9-10.

Dr. Brassard performed a total right hip replacement on Ms. McCoy on December 6, 2007. Ex. A, McCoy Records, at AAMC 192. Ms. McCoy was fifty-five years old at the time of her right hip replacement. *Id.* Dr. Brassard chose a Biomet M2a Magnum metal-on-metal hip implant for Ms. McCoy's surgery. Ex. A, McCoy Records, at AAMC 182. Ms. McCoy agreed with Dr. Brassard's use of a metal-on-metal hip implant, but she did not otherwise participate in the selection of her implant and trusted Dr. Brassard to choose the device. *See* Deposition of Joanna McCoy at 55:8-17; 60:7-21, attached hereto as "**Exhibit B**."

B. The Biomet M2a Magnum

The Biomet M2a Magnum used in Ms. McCoy's right total hip replacement surgery is a large-head metal-on-metal articulating hip implant. The Biomet M2a Magnum contains three components: a femoral head, a taper insert (that affixes the head to the femoral stem), and an acetabular cup. *See* Deposition of Dr. Marc Brassard at 21:10-24, attached hereto as "**Exhibit C**." The articulating head and acetabular cup are made from cobalt chrome molybdenum (CoCrMo) alloy. *See* Instructions for Use (IFU), attached hereto as "**Exhibit D**." The taper insert is made of a titanium alloy. *Id*. The acetabular cup, which is seated in the hip, is treated with a titanium Porous Plasma Spray. *Id*. A picture of the M2a Magnum is set forth below in Figure 1.

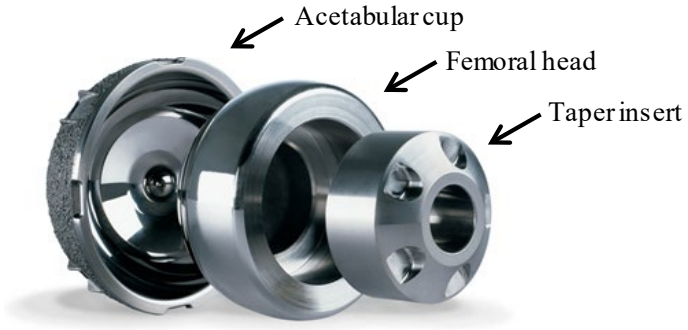

Figure 1. M2a Hip Replacement

Biomet included an FDA-mandated package insert or Instructions for Use ("IFU")[4] with its M2a products, including Ms. McCoy's Magnum device. *See generally* Defendant Fact Sheet ("DFS"), attached hereto as "**Exhibit E**"; Ex. D, IFU. The IFU for Ms. McCoy's Magnum identified several possible adverse effects and risks, including:

> 1. Material sensitivity reactions. Implantation of foreign material in tissues may result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant. A low incidence of metal hypersensitivity has been reported with failed metal on metal implants. The clinical relevance of these findings is unclear, and it is not known whether metal hypersensitivity causes implant failure.
>
> 2. Early or late postoperative infection and allergic reaction.
>
> 4. Loosening or migration of the implants may occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity.
>
> 10. Fretting and crevice corrosion may occur at interfaces between components.
>
> 11. Wear and/or deformation of articulating surfaces.
>
> 15. Elevated metal ion levels have been reported with metal-on-metal articulating surfaces. Although mechanical testing demonstrates that metal-on-metal articulating surfaces produce a relatively low amount of particles, the total amount of particulate produced in vivo throughout the service life of the implants remains undetermined. The long-term biological effects of the particulate and metal ions are unknown.

The IFU further stated:

> Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. Malalignment of the

[4] In the United States, medical device labels are highly regulated by the Food and Drug Administration. 21 C.F.R. § 801 (Medical Device Labeling); (*see, e.g.*, Labeling Regulatory Requirements for Medical Devices, HHS Publication FDA 89-4203, located at https://www.fda.gov/media/74034/download). All medical devices in the United States must include "adequate directions for use" (referred to in practice as "Instructions for Use" or "IFU") which means "directions under which the layman can use a device safely and for the purposes for which it is intended." 21 C.F.R. §801.5.

> components or inaccurate implantation may lead to excessive wear and/or failure of the implant or procedure.

See Ex. D, IFU. Dr. Brassard does not specifically recall whether he read the IFU prior to Ms. McCoy's implantation surgery. *See* Ex. C, Brassard Dep. at 31:10-20. However, Dr. Brassard would commonly review this type of information that accompanied the products he was using. Ex. C, Brassard Dep. at 31:17-20. As an orthopedic surgeon, he also was independently of the risks of material sensitivity reactions, infection, and implant loosening. *See* Ex. C, Brassard Dep. 32:12-19; 37:15-39:11

Biomet also made a Surgical Technique available for reference on optimal use of its M2a products, including Ms. McCoy's Magnum device. *See generally* Ex. E, DFS; Surgical Technique, attached hereto as "**Exhibit F**." The Surgical Technique for Ms. McCoy's M2a Magnum identified the preferred reaming technique for the acetabular cup:

> According to the surgeon's judgment of bone stock, the M²a-Magnum™ cup's hemispherical design is intended to achieve stable fixation with a 1-2 mm under ream (i.e., ream to 54-55mm, implant a 56mm cup).

See Ex. E, Surgical Technique. This guide also recommends placing the cup at 40 to 45 degrees of abduction (inclination) to achieve the optimal range of motion, although final placement is dependent on surgeon preference. *See id.*

C. Ms. McCoy's medical course and right hip revision surgeries

After Ms. McCoy's right hip surgery, Dr. Brassard reported that her hip was overall doing well – she was back to all her normal activities, including working, without difficulty. Ex. A, McCoy Records at TOSPB 12. Three months post-operatively, Ms. McCoy noticed a leg length discrepancy, with her right leg slightly longer than her left. *Id.*

Ms. McCoy next saw Dr. Brassard after falling on concrete at a neighbor's house on May 25, 2008, landing directly on her knee and pushing up on her hip. Ex. A, McCoy Records at

TOSPB 14; POA 5. Ms. McCoy's fall caused her severe hip and groin pain and pain with range of motion. *See id.* No right hip alignment problems were noted that day by Dr. Brassard. *See id.*

Approximately ten months after her right hip replacement surgery, in October 2008, Ms. McCoy reported renewed left hip pain and low back pain. Ex. A. McCoy Records at TOSM2 10. Her right hip was doing well at this time – she reported a little tenderness but continued improvement with orthotics to address her leg length discrepancy. Ex. A, McCoy Records at TOSM2 8.

For the next year and a half, Ms. McCoy sought medical treatment from numerous physicians for relief from persistent back pain, bilateral hip pain, sciatic joint pain, and fibromyalgia. *See* Ex. A, McCoy Records, at EdMcL 10, 12; INTE 6; DGH 165; CliffS 4; JHH 4, 7, 22; EdMcL 11. On July 10, 2009, Ms. McCoy stated that the pain she was experiencing at that time and for which she was seeking treatment was different from the pain which led her to undergo her right hip replacement surgery. Ex. A, McCoy Records at JHH 15. In fall 2009, she reported renewed right hip pain and sciatic joint pain. Ex. A, McCoy Records at MBSD 6. On March 22, 2010, Dr. Brassard saw Ms. McCoy again. He noted that Ms. McCoy had multiple issues with her back, sciatic nerve, SI joint, and greater trochanteric bursa area which were not resolved with steroid injections. Ex. A, McCoy Records at TOSPB 20.

Ultimately, Dr. Frank Ebert examined Ms. McCoy on April 17, 2010. He observed a ¾ inch leg length discrepancy (Ms. McCoy's left leg being longer than her right), (2) a change in the vertical orientation of the right hip acetabular component from 45 to 90 degrees on radiographs, consistent with loosening, and (3) osteolysis of the femur. Ex. A, McCoy Records, at UMOSM 11. Dr. Ebert recommended Ms. McCoy undergo revision surgery to replace the acetabular component. *Id.*

On May 10, 2010, Dr. Ebert performed revision surgery on Ms. McCoy's right hip. Ex. A, McCoy Medical Records, at UMH 936. Dr. Ebert removed the acetabular shell and implanted a temporary spacer acetabular component after observing the presence of purulent fluid. *Id.* Dr. Ebert's postoperative diagnosis was "failed right hip acetabular component secondary to infection." *Id.* He performed a debridement synovectomy and debridement with jet lavage and water pick. *Id.* Ms. McCoy was discharged after surgery with a final diagnosis of an infected right hip. Ex. A, McCoy Records, at UMH 887.

Dr. Ebert performed a second right hip revision on March 1, 2011. Ex. A, McCoy Records, at UMH 422. Dr. Ebert implanted a new acetabular shell with a polyethylene liner in Ms. McCoy's right hip. *Id.* On November 8, 2011, Ms. McCoy underwent left hip replacement surgery performed by Dr. Ebert. Ex. A, McCoy Records, at UMH 111.

D. Plaintiffs' allegations against Biomet

On January 24, 2019, Plaintiffs filed their Amended Complaint against Biomet alleging various products liability claims regarding the Biomet M2a Magnum hip replacement system that was implanted in Ms. McCoy's right hip. *See generally*, Doc. No. 43, Compl. Central to all of Plaintiffs' product liability causes of action against Biomet is their claim that the M2a Magnum "suffers from defects that cause excessive amounts of cobalt and chromium to corrode and wear from the surfaces of the acetabular cup, the femoral head, and the taper sleeve, which in turn causes the hip implant to fail and the surrounding tissue and bone to die." *Id.* at ¶ 1. Through the testimony of their retained expert Dr. Jeffrey Shapiro, Plaintiffs particularly allege Ms. McCoy suffered an adverse tissue reaction to metal debris from her right M2a Magnum device which led to premature failure and the need for revision surgeries. Through the testimony of revision surgeon Dr. Ebert, Plaintiffs allege alternatively that the M2a Magnum acetabular cup failed to ingrow, ultimately causing Ms. McCoy's acetabular cup to migrate and require revision. In sum, Plaintiffs

claim that the Magnum Device caused Ms. McCoy "severe pain and [s]he was forced to undergo costly and painful revision surgery." Compl. at ¶ 95.

E. Plaintiffs' Expert Witnesses

On May 15, 2019, Plaintiffs served their Plaintiffs' Expert Disclosures Pursuant To Federal Rule of Civil Procedure 26, designating Jeffrey M. Shapiro, M.D. (orthopedic surgeon) – as a retained expert – and Frank Ebert, M.D. (orthopedic surgeon) – as a non-retained expert – to testify as to specific causation. *See generally* Plaintiffs' Expert Disclosures Pursuant To Federal Rule of Civil Procedure 26, attached hereto as "**Exhibit G**." Plaintiffs also designated Mari Truman, P.E., George S. Kantor, M.D., and Francis H. Gannon, M.D. as their retained common-issue experts. *Id.* These retained common-issue experts submitted their common-issue reports in the M2a MDL, *In re: Biomet M2a Magnum Hip Implant Products Liability Litigation*, 3:12-MD-2391, Finally, Plaintiffs additionally designated "all medical providers who have been or will be deposed in this case" as non-retained experts. *Id.*

III. THE SUMMARY JUDGMENT STANDARD

Summary judgment is "designed to secure the just, speedy and inexpensive determination of every action." *Celotex Corp. v. Catrett,* 477 U.S. 317, 327 (1986) (internal citations and quotations omitted); *see Sibley v. Lutheran Hosp. of Md., Inc.*, 871 F.2d 479, 483 n.9 (4th Cir. 1989). The function of summary judgment is to "pierce the pleadings and to assess the proof in order to see whether there is a genuine issue for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (quoting Advisory Committee Note to 1963 Amendment to Fed. R. Civ. P. 56(e)). Summary judgment is correctly granted where there is no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56; *Matsushita Elec. Indus. Co.,* 475 U.S. at 586–67. "[T]he mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary

judgment; the requirement is that there be no *genuine* issue of material fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986) (emphasis in original).

To overcome a motion for summary judgment, "the non-moving party must 'do more than simply show that there is some metaphysical doubt as to the material facts,'" but rather "must come forward with specific facts showing that there is a *genuine issue for trial*." *Matsushita Elec. Indus. Co.,* 475 U.S. at 586 (emphasis in original) (internal citations and quotations omitted). Further, as the non-moving parties, Plaintiffs are only entitled to those inferences reasonably drawn from the facts. *See, e.g.*, *Gordon v. Kidd*, 971 F.2d 1087, 1097 (4th Cir. 1992), *as amended* (July 7, 1992). "[A] party cannot create a genuine dispute of material fact through mere speculation or compilation of inferences." *Chung Shin v. Shalala*, 166 F. Supp. 2d 373, 375 (D. Md. 2001) (citing *Deans v. CSX Transportation, Inc.*, 152 F.3d 326, 330-31 (4th Cir. 1998)).

As the moving party, Biomet has the burden of identifying the portions of the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, [which] show there is no genuine issue as to any material fact and that [Biomet] is entitled to judgment as a matter of law." *Celotex Corp.*, 477 U.S. at 322. Once the moving party has carried its burden, "[t]he party opposing a properly supported motion for summary judgment may not rest upon mere allegations or denials of [its] pleading, but must set forth specific facts showing that there is a genuine issue for trial." *Rivanna Trawlers Unlimited v. Thompson Trawlers, Inc.*, 840 F.2d 236, 240 (4th Cir. 1988). In fact, the party opposing summary judgment must show that there is sufficient evidence to support a jury verdict in its favor. *Anderson,* 477 U.S. at 249. Under these well-established principles, Biomet is entitled to summary judgment as a matter of law.

IV. ARGUMENT

A. Plaintiffs' manufacturing defect claims fails as a matter of law because Plaintiffs have not identified any manufacturing defect in Ms. McCoy's M2a Magnum implant.

The Court should dismiss Plaintiffs' manufacturing-based claims[5] for lack of evidence. To establish a manufacturing defect, a plaintiff must demonstrate that there was an error in the manufacturing process and the product is in a condition not intended by the seller. *Phipps v. General Motors Corp.*, 363 A.2d 955, 959 (Md. 1976). In other words, the product must reach the plaintiff not in its intended condition. *See id.*

Plaintiffs have no evidence of a manufacturing defect in Ms. McCoy's M2a Magnum. Plaintiffs' retained case-specific expert Dr. Shapiro offered no opinions as to a manufacturing defect. *See generally* Report of Dr. Jeffrey Shapiro ("Shapiro Report"), attached hereto as "Ex**hibit H**." Plaintiff's treating physician, Dr. Ebert, testified he had no opinions as to whether there was a manufacturing defect in Ms. McCoy's device. Deposition of Dr. Frank Ebert ("Ebert Dep."), attached hereto as "**Exhibit I**," 67:17-21. Similarly, Plaintiff's common-issue experts did not inspect Ms. McCoy's device, nor do they offer opinions specific to Ms. McCoy or her device.

In sum, Plaintiffs have no evidence of a manufacturing defect. The Court should dismiss Plaintiffs' claims premised on alleged manufacturing defects as a matter of law.

B. Biomet is entitled to summary judgment on all of Plaintiffs' claims for lack of admissible expert testimony establishing medical causation.

Medical causation—establishing a causal link between a product defect and a plaintiff's injuries—is an essential element in all product liability cases.[6] All of Plaintiffs' claims require

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[5] *See* Compl, Count I at ¶¶ 99-109 (strict liability as it relates to manufacturing defect) and Count II at ¶¶ 110-117 (negligence as it relates to manufacturing) – alleging defects in the manufacturing of Ms. McCoy's M2a Magnum.

[6] Maryland has adopted Section 402A of the Restatement (Second) of Torts for strict liability claims, which requires, among other things, a plaintiff to prove "that the defect was a cause of the injuries." *Owens-Illinois, Inc. v. Zenobia*, 601 A.2d 633, 639 (Md. 1992). For product liability claims

evidence linking an alleged product defect to an alleged injury. *See, e.g.*, *Doe v. Miles Labs., Inc.*, 675 F. Supp. 1466, 1475 (D. Md. 1987) (holding under any products liability theory, a plaintiff is required to prove "a causal relation between the defect and the injury"), *aff'd*, 927 F.2d 187 (4th Cir. 1991); *Fitzgerald v. Smith & Nephew Richards, Inc.*, No. CIV. JFM-95-3870, 1999 WL 1489199, *2 n.2 (D. Md. Dec. 30, 1999) (explaining that exclusion of expert testimony in spinal implant products liability case would be "fatal to all of [plaintiff's] claims since evidence of medical causation is necessary as a bare minimum on any claim"), *aff'd sub nom. Fitzgerald Smith & Nephew, Inc.*, 11 F. App'x. 335 (4th Cir. 2001). Further, any medical causation evidence must be based upon some objective, scientific methodology and cannot be of a "wholly conclusory" nature. *See id.* at *3 (citing *M & M Medical Supplies v. Pleasant Valley Hosp.*, 981 F.2d 160, 165 (4th Cir. 1992)).

Plaintiffs' claims regarding Ms. McCoy's M2a Magnum device involve complex medical and scientific issues which require expert testimony to establish product defect and negligence (design, manufacturing, or warnings) and medical causation (design, manufacturing, or warnings). *See Jones v. Reichert Jung, Inc.*, 211 F. Supp. 2d 661, 667 (D. Md. 2002) ("Maryland courts have adopted the general rule that expert testimony is required when the subject of the inference that a product is defective is particularly related to some science or profession that it is beyond the ken of the average layman."); *Miskin v. Baxter Healthcare Corp.*, 107 F. Supp. 2d 669, 672 (D. Md. 1999) (explaining that expert testimony is necessary when "the evidence relating to causation involves technical medical questions beyond the common knowledge of laypersons"), *aff'd*, 213

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sounding in negligence, a plaintiff must establish that the loss or injury proximately resulted from the defendant's breach of the duty. *Gourdine v. Crews*, 405 Md. 722, 738, 955 A.2d 769, 779 (2008). Express and implied warranty claims likewise require plaintiff to prove causation. *See Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 420 (D. Md. 2001) (explaining that as part of an express warranty claim, a plaintiff must show the lack of conformity caused the injury suffered); *Lloyd v. General Motors Corp.*, 916 A.2d 257, 286 (Md. Ct. App. 2007) (same for implied warranty claim).

F.3d 632 (4th Cir. 2000); *Mohammad v. Toyota Motor Sales, U.S.A., Inc.*, 947 A.2d 598, 607 (Md. Ct. Sp. App. 2008).

Maryland courts have held that a wide variety of product defect claims require expert testimony to prove causation, including allegedly defective implant cases. *See, e.g.*, *Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 95-96 (D. Md. 1989) (requiring expert testimony on issue of defectiveness of breast implant), *aff'd sub nom. Lee v. Baxter Health Care Corp.*, 898 F.2d 146 (4th Cir. 1990); *Wood v. Toyota Motor Corp.*, 760 A.2d 315, 318–19 (Md. 2000) (requiring expert testimony on the issue of defectiveness of air bag). Medical device product defect cases almost categorically require case-specific expert testimony because they raise causation issues that are beyond the knowledge of a layperson. *Miskin*, 107 F. Supp. 2d at 672 (explaining expert testimony is necessary when "the evidence relating to causation involves technical medical questions beyond the common knowledge of laypersons").

Here, Plaintiffs' product liability claims require expert opinions on whether any claimed defect in the M2a Magnum (or Biomet's negligence) *caused* the need for Ms. McCoy's revision surgery and injuries. Plaintiffs cannot meet their burden because they have no admissible expert evidence causally linking a specific defect in the M2a Magnum device to Ms. McCoy's claimed injuries. With the exclusion of their medical experts' key opinions and lack of other admissible medical causation testimony, all of Plaintiffs claims fail as a matter of law.

1. Plaintiffs' retained case-specific expert's causation opinions are inadmissible and cannot establish medical causation.

Biomet contemporaneously filed *Daubert* motions with this summary judgment motion seeking to exclude the proposed trial testimony of Plaintiffs' retained case-specific expert Dr. Jeffrey Shapiro. Plaintiffs' claims about Ms. McCoy's M2a Magnum device involve complex medical and scientific issues which require expert testimony to establish product defect and

negligence (design, manufacturing, or warnings) and medical causation (design, manufacturing, or warnings). *See Jones*, 211 F. Supp. 2d at 667. With the exclusion of Dr. Shapiro's key opinions, *all* of Plaintiffs' claims fail as a matter of law.

As more fully demonstrated in Biomet's *Daubert* motion, Dr. Shapiro does not provide admissible opinions as to what caused Ms. McCoy's hip implant to fail, leading to her need for revision surgeries. It is axiomatic that where an element of a claim requires expert testimony and the court excludes the expert who was to provide that testimony, the claim necessarily fails as a matter of law. *See, e.g.*, *Miskin*, 107 F. Supp. 2d at 676 (granting summary judgment where plaintiff failed to provide admissible expert testimony that her breast implants were defective and caused her to develop Crohn's syndrome).

2. Plaintiffs' non-retained treating experts do not establish medical causation.

Plaintiffs' designation of revision surgeon Dr. Frank Ebert and blanket designation of unnamed "medical providers" (see Ex. G, at 2-3) as non-retained experts does help them establish medical causation. Indeed, Dr. Ebert and Ms. McCoy's other unnamed treaters do not provide admissible testimony regarding causation. Ex. G, at 2-3.

Any opinion from these non-retained treating experts is expressly limited to those formed during his or her diagnosis and treatment of Ms. McCoy.[7] *See Hare v. Opryland Hospitality, LLC*, No. DKC 09-0599, 2010 WL 3719915, at *5 (D. Md. Sept. 17, 2010) ("If a treating physician intends to testify regarding things which are not based on their observations during the course of treating the patient's illness or injury, they must appropriately disclose those opinions in an expert

[7] Biomet further objects to the extent Plaintiffs seek to use the purported opinions her non-retained medical providers in response to Biomet's Motion for Summary Judgment or at trial because she has not properly disclosed the subject matter on which such providers are expected to present evidence and did not provide a summary of the facts and opinions upon which such witnesses are expected to testify as required by Federal Rule of Civil Procedure 26(a)(2)(C). *See* Ex. G,at 3.

report"). A party is relieved from the obligation to submit a Rule 26(a)(2)(B) expert report for a physician only if "the source of the facts which form the basis for a treating physician's opinions derive from information learned during the actual treatment of the patient—as opposed to being subsequently supplied by an attorney involved in litigating a case involving the condition or injury . . . ." *Sullivan v. Glock, Inc.*, 175 F.R.D. 497, 501 (D. Md. 1997). Further, "[A] treating physician's testimony regarding causation of an injury or illness is subject to the same standards of scientific reliability that govern the testimony of experts hired solely for purposes of litigation." *Hare*, 2010 WL 3719915, at *5 (citing *Perkins v. United States*, 626 F. Supp. 2d 587 n.7 (E.D. Va. 2009)); *see also Sullivan*, 175 F.R.D. at 508. When there is "too great an analytical gap between the data and the opinion proffered," the opinion is subject to exclusion. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Treating physicians' opinions, particularly on causation, should be excluded if the treating physician does not conduct a reliable and proper differential diagnosis. *See, e.g.*, *Zellers v. NexTech Northeast, LLC*, 533 Fed. Appx. 192, 197-98 (4th Cir. 2013) (finding employee's treating physician causation testimony unreliable because she did not conduct a proper differential diagnosis).

Applying these standards, none of Ms. McCoy's treating physicians (Dr. Ebert and the other unnamed treaters) has offered an admissible causation opinion linking an alleged defect in the M2a Magnum device to Ms. Ms. McCoy's claimed injuries. For example, as more fully demonstrated in Biomet's *Daubert* motion to exclude Dr. Ebert, his causation opinions in his 2015 affidavit exceed the scope of treating physician testimony. *See* Affidavit of Dr. Frank Ebert ("Ebert Aff."), attached hereto as **Exhibit "J."** Dr. Ebert tried in 2015 to retroactively re-analyze his diagnoses and observations regarding Ms. McCoy's right hip revision surgery in 2011 to opine on the cause of Ms. McCoy's revision surgery and offer newly-formed opinions. But such a

causation opinion is beyond the permissible scope of treating physician testimony and should be stricken without a complete Rule 26(a)(2)(B) expert disclosure. Moreover, Dr. Ebert's purported causation opinion should be excluded because it is *ipse dixit*, based only on his speculative opinion and unsupported by any personal experience with the M2a Magnum, testing, or scientific literature. Dr. Ebert's causation opinions fail to meet the strictures of Federal Rule of Evidence 702 and *Daubert* and its progeny and should be excluded.

Further, Plaintiff's implanting surgeon Dr. Marc Brassard did not even attempt to offer a causation opinion. Dr. Brassard testified that he has no opinion on whether the M2a Magnum was defectively designed. *See* Ex. C, Brassard Dep. 69:19-22. Moreover, Dr. Brassard testified that as a fact witness, he did not intend to offer any opinions on the cause of Ms. McCoy's right hip revision surgeries or the findings therefrom. *Id*. at 68:23-69:5.

3. Plaintiffs' retained common-issue experts do not establish specific medical causation.

Plaintiffs' common-issue experts – Mari Truman, P.E., George S. Kantor, M.D., and Francis H. Gannon, M.D. – do not help Plaintiffs meet their burden of establishing medical causation either. Indeed, they address *only* common issues and none of them offer any opinion that any specific defect in the M2a Magnum was the medical cause of Ms. McCoy's injuries and need for revision surgeries. *See* Ex. G, at 1-2 (not describing or attaching any reports from common-issue experts).

4. The only admissible expert evidence – Biomet's evidence – establishes that Ms. McCoy's M2a Magnum did not cause her alleged injuries.

The testimony of Biomet's case-specific engineering expert, Dr. Steven Kurtz, and Biomet's medical experts, Dr. Thomas Fleeter and Dr. Thomas Bauer affirmatively establishes that Ms. McCoy's need for revision surgery was related to biomechanical, clinical, and patient

factors, not the M2a Magnum device itself. Because the undisputed evidence disproves causation, summary judgment should be entered in Biomet's favor.

Biomet has presented admissible expert testimony establishing that suboptimal press-fit of Ms. McCoy's M2a Magnum acetabular cup at implantation hindered bony ingrowth and caused it to subsequently loosen, requiring revision surgeries. A periprosthetic infection, observed at the May 10, 2010 revision surgery was another factor that likely contributed to the need for Ms. McCoy's right hip revision surgeries.

Biomet designated and produced the expert report of its biomechanical expert, Dr. Steven Kurtz, who analyzed the impact of Ms. McCoy's initial M2a Magnum acetabular cup fitting on the subsequent mechanical loosening of her acetabular cup. *See* Declaration and Expert Report of Dr. Steven M. Kurtz ("Kurtz Report") at 41-42, attached hereto as "**Exhibit K**." Dr. Kurtz explains lack of initial stable fixation of the acetabular cup at implant is a key factor that can cause the Magnum cup to subsequently loosen. *Id.* at 41. Stable press fit cup fixation of the M2a Magnum depends on reaming depth and the quality and extent of bone. *Id.* Biomet's surgical guide applicable to Ms. McCoy's M2a Magnum contains language on the recommended acetabulum reaming technique to ensure this press fit fixation:

> According to the surgeon's judgment of bone stock, the M²a-Magnum™ cup's hemispherical design is intended to achieve stable fixation with a 1-2mm under ream (i.e., ream to 54-55mm, implant a 56mm cup)

Ex. F, Surgical Technique. A 1 mm under-ream is called the "gold standard" for achieving implant stability. Ex. K, Kurtz Report at 41. Using Biomet's recommended under-ream technique, the acetabulum (where the Magnum cup would be impacted into) would have been reamed to 44-45mm to achieve full circumferential press it and stable initial fixation of a 46 mm Magnum cup. *Id.* However, rather than under-reaming, implanting surgeon Dr. Brassard chose to perform

a "line-to-line" ream during the implant of Ms. McCoy's M2a Magnum. Ex. A, McCoy Records, at AAMC 192. He reamed the acetabulum "from 40mm to 46mm and a 46mm Magnum shell was impacted into place." Ex. K, Kurtz Report at 30; Ex. A, McCoy Records, at AAMC 192.

Another factor that likely contributed to a less than optimal initial press-fit fixation of the Magnum cup to Ms. McCoy's hip socket was the angle at which the Magnum cup was implanted. Dr. Kurtz determined the initial Magnum cup position was 32 degrees of abduction from review of imaging at the time of implant. Ex. K, Kurtz Report at 42. Biomet's surgical guide for the M2a Magnum recommends an abduction angle of 40 to 45 degrees when impacting the Magnum cup into the hip socket. Ex. F, Surgical Technique. The shallower abduction angle led to superior overhang of Ms. McCoy's cup. Ex. K, Kurtz Report at 42.

Nominal "line-to-line" contact between the Magnum cup and Ms. McCoy's hip socket combined with Magnum cup's abduction angle below Biomet's recommendation are both key factors that increased Ms. McCoy's risk of suboptimal initial fixation of her Magnum cup. Ex. K, Kurtz Report at 42. Also, patient factors, such as Ms. McCoy's history of falling, also may have potentially impacted the quality of the initial fixation. *Id.* This suboptimal fixation of Ms. McCoy's Magnum cup contributed to the loosening and migration of her Magnum cup, requiring revision. *Id.*

Further, Biomet produced the expert testimony of Dr. Fleeter, an orthopedic surgeon, who performs hip replacement surgeries and teaches on the topic of hip implants. Dr. Fleeter opines that based on his analysis of Ms. McCoy's medical records, x-rays, and deposition, her need for revision surgeries was unrelated to the M2a Magnum device itself. *See* Declaration and Expert Report of Thomas B. Fleeter at 5-7, attached hereto as "**Exhibit L.**" Instead, Dr. Fleeter concludes that Ms. McCoy "had failure of porous ingrowth of the right hip acetabular component that

ultimately resulted in the cup moving into a vertical position." *Id.* at 6. Like Dr. Kurtz, Dr. Fleeter also recognized that "[p]roper preparation of the bony acetabulum is critical to promote bone ingrowth." *Id.* Dr. Fleeter concludes that "[r]eaming line-to-line, like Dr. Brassard did, over-reams the acetabulum, resulting in a less tight fit and increasing the risk of failure of [bony] ingrowth." *Id.* Dr. Fleeter believes Ms. McCoy "had failure of porous ingrowth of her right hip acetabular component that ultimately resulted in the cup moving into a vertical position," requiring revision. *Id.*

Lastly, Biomet produced the expert testimony of pathologist Dr. Thomas Bauer, who concludes that another factor leading to Ms. McCoy's right hip failure was likely periprosthetic infection. *See* Declaration and Expert Report of Dr. Thomas Bauer at 27, attached hereto as "**Exhibit M**." Dr. Bauer reviewed slides of specimens taken during Ms. McCoy's revision surgeries. He agreed with the local pathologist's finding of a high tissue concentration of neutrophils from the sample taken during the initial May 10, 2010 revision surgery, far above the threshold recommended for a finding of infection by the American Academy of Orthopedic Surgeons. *Id.* This, combined with Dr. Ebert's impression of "purulent fluid" indicating infection during this revision surgery, suggests that one factor leading to Ms. McCoy's ultimate right hip arthroplasty failure was likely periprosthetic infection. *Id.*

Because Dr. Ebert's and Dr. Shapiro's causation opinions are inadmissible, Dr. Kurtz's, Dr. Fleeter's, and Dr. Bauer's opinions on medical causation are unrefuted. Ms. McCoy's M2a Magnum cup was implanted in a suboptimal position and had a less tight fit into her acetabulum due to line-to-line reaming, which resulted in the Magnum cup's loosening and migration and her need for revision surgery. Various patient factors and a periprosthetic infection also likely impacted the functioning of Ms. McCoy's right hip implant and her need for revision surgery. Put

simply, a combination of biomechanical, clinical, and patient factors caused Ms. McCoy's need for revision surgery, not any alleged defect in the M2a Magnum.

In sum, Plaintiffs' retained case-specific expert Dr. Shapiro's opinions do not prove medical causation, none of Plaintiffs' common-issue experts even purports to offer specific causation opinions, Ms. McCoy's treating medical providers testimony, including the testimony of Dr. Ebert, is limited to their medical treatment of Ms. McCoy and they cannot offer admissible causation opinions, and Biomet's expert evidence disproves Plaintiffs' claims. Without admissible expert testimony that a defect *caused* Ms. McCoy's injuries, Plaintiffs cannot prove the essential element of medical causation. There is no genuine issue of material fact on causation, and Biomet is entitled to summary judgment on *all* of Plaintiffs' claims for this reason alone.

5. Even if Dr. Ebert and Dr. Shapiro's case-specific opinions were admissible, all of Plaintiffs' claims still fail because their testimony does not link a specific product defect to Ms. McCoy's claimed injuries.

Irrespective of whether the Court grants Biomet's Daubert motions to exclude Plaintiffs' case-specific experts, Biomet is nevertheless entitled to summary judgment on all of Plaintiffs' claims because no expert links an alleged defect or negligence to Ms. McCoy's case. The fact that Ms. McCoy's M2a Magnum was revised is not enough to establish a product defect. "Proof of a defect in a products liability case must rise above speculation and recovery cannot be predicated on a presumption from the mere happening of an accident." *Lee*, 721 F. Supp. at 96. "[E]very side effect or adverse reaction does not indicate either that the product is unreasonably dangerous and defective, or that the manufacturer was negligent in the promotion and sale of its product." *Perlov v. G.D. Searle & Co.*, 621 F. Supp. 1146, 1148 (D. Md. 1985). Accordingly, Plaintiffs must offer some evidence beyond the product's failure itself to prove that it is defective and unreasonably dangerous. *See Lee*, 721 F. Supp. at 96. This is particularly true with medical

devices because a patient's medical and surgical history can impact the survivorship of a device. Identifying the cause or causes of a hip implant to fail – design, biomechanical factors, patient factors, or otherwise – is not within an average juror's knowledge and experience.

Even if the Court considers Plaintiffs' case-specific expert testimony, their testimony fails to link any specific product defect to Ms. McCoy's case. In fact, Dr. Shapiro and Dr. Ebert could do not even agree what alleged mode of device failure or alleged defect caused Ms. McCoy's acetabular cup to loosen and migrate – lack of ingrowth vs. adverse local tissue reaction.

a. Dr. Frank Ebert

Dr. Ebert opines that "the [] revision surgery was more likely than not necessary due to symptoms linked to the metal-on-metal design of my patient's Biomet device." Ex. J, Ebert Aff. At his deposition, Dr. Ebert clarified that Ms. McCoy's M2a Magnum acetabular cup failed because it didn't ingrow, a concept describing bone growth into the acetabular cup to achieve stable fixation. With no supporting evidence, Dr. Ebert offers the conclusory opinion that the M2a Magnum was poorly designed because there was no bony ingrowth on the back of the acetabular cup. Ebert Dep. at 60:7-12. But Dr. Ebert's opinion is wholly circular: the loosening occurred because of a lack of ingrowth attributable to the design, and the design is faulty because there was no ingrowth. *Id*. 59:18–61:7.

Moreover, he could not point to a specific defect in the Magnum that purportedly caused the lack of ingrowth. Indeed, Dr. Ebert testified that lack of ingrowth is not something that is unique to metal-on-metal implants, much less the M2a Magnum. *Id*. at 18:15-17. He admitted he did no testing or studies to rule out other causes for the cup loosening. *Id*. at 60:13-15. In fact, he could not point to *what specifically* about the M2a Magnum design was defective.

> Q: Do you think that [failure to ingrow] was due to the fact that it was a metal-on-metal implant?

A: I don't know whether that was, in fact, the case or not, but it didn't ingrow.

Id. at 59:21-24. Despite having no personal experience observing this type of hip failure with the M2a Magnum, Dr. Ebert did not conduct his own studies comparing bone growth of M2a Magnum implants with other hip implants and could point to no scientific literature, peer-reviewed or otherwise, discussing the issue of ingrowth with the M2a Magnum acetabular cup. *Id*. at 62:11-63:16.

Dr. Ebert's opinion alleging design defect is premised on guesswork, not facts. Dr. Ebert could not recall ever implanting an M2a Magnum hip system. *Id*. at 12:25-13:12. Ms. McCoy's M2a Magnum is the only M2a Magnum he's revised and, therefore, the *only* M2a Magnum he has observed that involved an acetabular cup loosening. *Id*. at 61:25-62:6. Further, Dr. Ebert has no experience designing metal-on-metal hip systems. *Id*. at 64:7-9. He does not consider himself an expert in metallurgy, material science, or tribology. *Id*. at 64:15-65:7. Dr. Ebert's *sole experience* with the Biomet M2a Magnum, during the revision of Ms. McCoy's M2a Magnum, is insufficient to allow him to develop a causal link between a *specific* defect in the M2a Magnum and Ms. McCoy's alleged injuries. Ms. McCoy's complained-of-injuries from lack of acetabular cup ingrowth and subsequent loosening was a potential risk that accompanied many orthopedic implants, not just metal-on-metal hips or the M2a Magnum device in particular. Plaintiffs cannot rely on Dr. Ebert to establish either product defect or causation.

b. Dr. Jeffrey Shapiro

Dr. Shapiro's opinion, that metallosis negatively affected Ms. McCoy's tissues, specifically the right hip abductor muscle group, and resulted in a need for revision surgery, is conclusory and cannot establish specific defect or medical causation. Dr. Shapiro outlined his primary findings of alleged defect ("metal-on-metal breakdown") and causation as follows:

> The classic findings on radiographs, as well as the findings at the timing of the operative procedures, are consistent with failure due to metal-on-metal breakdown, with adverse tissue reaction resulting in a failed hip replacement. There is no other explanation for the failure of her hip, such as implant malposition, trauma, infection, etc.

Ex. H, Shapiro Report at 4. But his opinions are directly contradicted by both the objective medical evidence and the testimony of revising physician Dr. Ebert. Dr. Shapiro cites two findings, radiographic findings and operative findings, that he opines are consistent with "metal-on-metal breakdown." *Id.* Dr. Shapiro admitted, though, that he did not even read Ms. McCoy's 2008 post-operative implantation radiographs from when ingrowth might have been shown. *See* Deposition of Dr. Jeffrey Shapiro ("Shapiro Dep.) at 43:20-24 ("it appears that the imaging I actually reviewed begins April 17th of 2010, which is at the time when the cup was already loose."); 44:5-12; 51:19-22, attached hereto as "**Exhibit N.**" Dr. Shapiro could not have accurately assessed defect and causation without review of Ms. McCoy's radiographic findings of her right hip after her right hip replacement surgery in December 2007 but before the acetabular cup loosening was observed in April 2010. There were several that Dr. Shapiro could have reviewed.

Looking to the operative findings, Dr. Shapiro's opinion that Ms. McCoy had an adverse tissue reaction caused from metallosis is directly contradicted by the testimony and revision surgery operative note of Dr. Ebert. In his May 10, 2010 revision surgery operative report, Dr. Ebert states the reason for the revision surgery was due to "obvious loosening of her right hip acetabular component." Ex. A, McCoy Medical Records, at UMH 936. Neither Dr. Ebert, nor any of Ms. McCoy's other treating physicians, conducted any metal ion testing on Ms. McCoy. On top of that, Dr. Ebert did not note the presence of any metallosis, metal staining, or muscle deficiencies. Ex. I, Ebert Dep. at 42:24–43:7. Dr. Ebert further found no evidence of tissue necrosis or pseudo tumors. Ebert Dep. at 43:8-12.

Dr. Shapiro opines there is simply no other explanation than "metal-on-metal break down" for Ms. McCoy's hip failure, including particularly implant malposition or infection. How could Dr. Shapiro rule out implant malposition when he never viewed radiographic findings before April of 2010, when Ms. McCoy's acetabular cup had already loosened? Similarly, how could Dr. Shapiro dismissively rule out infection, when the May 10, 2010 revision operative note lists postoperative diagnosis as "Failed right acetabular component secondary to infection" and Dr. Ebert's observations in the operating room led him to insert a temporary antibiotic spacer into Ms. McCoy's right hip? *See* Ex. A, McCoy Medical Records, at UMH 936. Dr. Ebert even explained, "This [purulent fluid] appeared to be gross infection and with the presence of this it was felt that the patient's loosening had been associated with the infectious process." Ex. A, McCoy Medical Records, at UMH 936. Dr. Shapiro's opinion, based on incomplete analysis of possible alternative reasons for Ms. McCoy's hip failure, combined with his disregard of Dr. Ebert's operative findings and subsequent testimony does not provide proof of a link between a specific product defect and Ms. McCoy's injuries.

C. Plaintiffs' warning claims fail as a matter of law because the M2a Magnum's IFU is adequate and for lack of causation.

Plaintiffs allege that Biomet failed to adequately warn of the risks of the M2a Magnum device – Count II (strict liability) and Count II (negligence). Under Maryland law, negligence and strict liability concepts "morph[] together" in failure to warn cases. *Gourdine v. Crews*, 955 A.2d 769, 782 (Md. 2008) ("Duty, thus, is an essential element of both negligence and strict liability causes of action for failure to warn."); *see Mazda Motor of Am., Inc. v. Rogowski*, 659 A.2d 391, 394 (Md. Spec. Ct. App. 1995) ("[I]t is true that a strict liability claim based on failure to warn bears a strong resemblance to a claim of negligence. Concepts of duty, breach, causation, and damages are present in both."), *cert. denied*, 340 Md. 501 (1995). Thus, to sustain both claims

Plaintiffs must prove that Biomet had a duty to warn Plaintiffs which Biomet breached, and Biomet's failure to warn caused Plaintiffs' injury.

Maryland courts apply the learned intermediary doctrine in cases involving prescription drugs and prescription medical devices. *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1231–32 (4th Cir. 1984) (applying doctrine to a failure to warn claim regarding a medical device*); Miller v. Bristol-Myers Squibb Co.*, 121 F. Supp. 2d 831, 838 (D. Md. 2000) (granting summary judgment of failure to warn claim in favor of breast implant manufacturer after applying doctrine to conclude manufacturer owed Plaintiff no duty to warn); *Hunt by Hunt v. Hoffman-La Roche, Inc.*, 785 F. Supp. 547, 550 (D. Md. 1992) ("Maryland courts have adopted the 'learned intermediary' rule under which a manufacturer of a prescription drug has a duty to warn only physicians, not patients, of potential risks associated with the use of the drug.") (collecting cases).

Under the learned intermediary doctrine, a medical device manufacturer "has no duty to warn the patient of the risks associated with products used under the supervision of a doctor." *Miller*, 121 F. Supp. 2d at 838; *see Brooks*, 750 F.2d at 1231-32; *Lee*, 721 F. Supp. at 95. Instead, a device manufacturer discharges its duty to warn the patient by warning the patient's physician of the risks associated with the product. *Miller*, 121 F. Supp. 2d at 838 ("The manufacturer's duty to warn is limited to adequately informing the patients' doctor of any risks associated with the product's use."); *Jeffries v. Bos. Sci. Corp.*, No. RWT 15-cv-3480, 2017 WL 2645723, at *5 (D. Md. June 2, 2017).[8] Further, a device manufacturer's warning to a treating physician is legally

[8] The duty to warn runs to the treating physician – the learned intermediary – because a prescribing physician "is in the best position to understand the patient's needs and assess the risks and benefits of a particular course of treatment." *Lee*, 721 F. Supp. at 95. In a case involving prescription medical devices such as the M2a Magnum, the implanting surgeon acts as a learned intermediary between the manufacturer and the ultimate consumer, and "[i]t is the physician's duty to remain abreast of product characteristics and, exercising an informed professional judgment, decide which facts should be told to the patient." *See Brooks*, 750 F.2d at 1232.

adequate when it explains the risk which the plaintiff alleges has caused the injury. *See Weinberger v. Bristol-Myers Co.*, 652 F. Supp. 187, 191 (D. Md. 1986).

Even if a manufacturer's warning is inadequate (*i.e.*, did not explain the risk that plaintiff complains of), a manufacturer will still *not* be liable if the physician knew of the risk independently. *See, e.g.*, *McClure v. Sci. Spinal*, 11 F. App'x 154, 159 (4th Cir. 2001) (applying Maryland law); *Ames v. Apothecon, Inc.*, 431 F. Supp. 2d 566, 572 (D. Md. 2006) ("Even if a label's warnings are inadequate, the doctrine protects a manufacturer from liability provided the doctor has been sufficiently warned from other sources."). Such a failure is not the proximate cause of the patient's injury if the prescribing physician already had knowledge of the risks that the allegedly insufficient warning should have communicated. Where a plaintiff's physician had independent knowledge of the risk, the causal link between an alleged failure to warn and the plaintiff's injury is broken because the physician had substantially the same knowledge as what would have been included in an adequate warning from a manufacturer.

Put simply, under the learned intermediary doctrine, a medical device manufacturer discharges its duty to warn by providing adequate warning to a patient's prescribing physicians and is otherwise relieved from liability for lack of causation if the prescribing physician had independent knowledge of the device's risks. An analysis of Biomet's IFU for the M2a Magnum, the learned intermediary doctrine, and proximate causation to the undisputed facts demonstrates that Biomet is entitled to summary judgment on Plaintiffs' warning claims for two reasons. First, Biomet's IFU specifically warns of the risks Plaintiffs claim caused Ms. McCoy's injuries. Therefore, the warnings are adequate as a matter of law. Second, Plaintiffs cannot establish that different warnings would have had any impact on Ms. McCoy's treatment because Dr. Brassard

already knew of the risks associated with metal-on-metal implants at the time of Ms. McCoy's right hip implant surgery.

6. Biomet's IFU is adequate and warns of the risks of "material sensitivity reactions," infection, and cup loosening and migration, among other risks.

At the crux of Plaintiffs' case is their claim that Ms. McCoy had an inflammatory reaction to metal wear from Ms. McCoy's M2a Magnum device. Biomet's M2a Magnum IFU addresses these risks:

- The IFU warns of "Material sensitivity reactions" as follows:

  Implantation of foreign material in tissues may result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant. A low incidence of metal hypersensitivity has been reported with failed metal on metal implants. The clinical relevance of these findings is unclear, and it is not known whether metal hypersensitivity causes implant failure.

  Ex. D, IFU, Possible Adverse Effects, ¶ 1.

- The IFU further warned of elevated metal ion levels:

  Elevated metal ion levels have been reported with metal-on-metal articulating surfaces. Although mechanical testing demonstrates that metal-on-metal articulating surfaces produce a relatively low amount of particles, the total amount of particulate produced in vivo throughout the service life of the implants remains undetermined. The long-term biological effects of the particulate and metal ions are unknown.

  Id., Possible Adverse Effects, ¶ 15.

- "Early or late postoperative, infection, and allergic reaction."

  Id., Possible Adverse Effects, ¶ 2.

Additionally, the M2a Magnum IFU addressed potential mechanical risks, including:

- "Wear and/or deformation of articulating surfaces." *Id.*, Possible Adverse Effects, ¶ 11.

- Loosening or migration of implants from loosening or malalignment. *See id.*, Possible Adverse Events, ¶

Plaintiffs' warning claims fail because it is undisputed that the IFU warns of the very complications that Plaintiffs claim Ms. McCoy experienced with her hip implant – adverse tissue reaction and cup loosening. *See* Ex. D, IFU. Because the M2a Magnum's IFU warned of the complications that Plaintiffs claim Ms. McCoy experienced with her hip implant, the warnings are adequate as a matter of law, and Biomet is entitled to summary judgment. *See Lee*, 721 F. Supp. at 95-96 (granting summary judgment in favor of defendant-manufacturer because package insert specifically warned of the danger Plaintiff endured).[9]

7. Plaintiff cannot establish that any alleged failure to warn caused Ms. McCoy's injuries.

Notwithstanding the adequacy of Biomet's IFU, Plaintiffs' warning claims fail for lack of causation. A plaintiff must show not only that the warnings were inadequate, but that the physician was otherwise unaware of the risks the defective warning should have communicated. *See McClure* 11 F. App'x at 159 ("[I]t is simply unsustainable to contend that a warning required to be given to treating physicians is defective because of a failure to warn when it is established that the physicians had knowledge of the risks that allegedly should have been included in the warning."). Plaintiffs cannot establish proximate causation – by demonstrating that a different warning would

[9] Another federal court recently concluded that Biomet's M2a Magnum warnings were adequate as a matter of law. *See* Order in *Nicholson v. Biomet, Inc.*, No. 18-CV-3057-CJW-KEM (N.D. Iowa Mar. 6, 2020), attached hereto as "**Exhibit O**" at 32–33. Like Plaintiffs here, the *Nicholson* plaintiff alleged that her M2a Magnum cup had loosened and migrated to a vertical position, which she argued led to excessive wear and an adverse tissue reaction. *See* Ex. N, *Nicholson* Order, at 33. The court found the warnings were adequate as a matter of law because they "indicate[d] that corrosion may occur between components, that elevated metal ion levels have been reported, that metallic wear debris may initiate a cellular response, and that loosening of the cup may occur." *Id.* That same reasoning applies here. Every adverse effect Ms. McCoy alleges she experienced in her right hip was specifically warned of in the M2a Magnum's IFU. Because the warnings are adequate as a matter of law, this Court should dismiss Plaintiffs' warnings claims.

have altered the behavior of Dr. Brassard (the learned intermediary) – because Dr. Brassard was already aware of the risk of injuries that Ms. McCoy experienced regardless of any warnings he received from Biomet.

Indeed, Dr. Brassard testified that in late 2007, at the time of Ms. McCoy's right hip implant surgery, he was *independently* aware of the risks of material sensitivity reactions, infection, and implant loosening. *See* Ex. C, Brassard Dep. 32:12-19; 37:15-39:11. Because Dr. Brassard was already aware at the time of Ms. McCoy's December 2007 hip implant surgery of the risks Plaintiffs complain of, Plaintiffs' warning claims fail as a matter of law. *See McClure v. Sci. Spinal*, 11 F. App'x at 159. In fact, Dr. Brassard testified that looking back, he still believes the M2a Magnum was the correct device for Ms. McCoy. *See* Ex. C, Brassard Dep. 54:8-13.[10]

Biomet is entitled to summary judgment on Plaintiffs' failure to warn claims because Biomet satisfied its duty to warn and Plaintiffs cannot prove proximate causation since Dr. Brassard was independently aware of the risks associated with the M2a Magnum.

D. Maryland law does not recognize a general negligence claim in the product liability context.

The Court should dismiss Plaintiffs' claim for general negligence (Count II) as a matter of law because Maryland does not recognize free-standing negligence claims in the product liability context. *See Moran v. Faberge, Inc.*, 332 A.2d 11, 19 (Md. Ct. App. 1975) (distinguishing between the "general negligence context" and "product liability cases" and discussing general negligence

[10] Further, Ms. McCoy's own testimony proves that even if Biomet somehow bypassed the learned intermediary and provided duplicative warnings directly to her (which Biomet was *not* obligated to do), her treatment would have been the same. Ms. McCoy testified that she trusted and relied on Dr. Brassard to select the correct implant for her and that she did not personally select the Biomet M2a Magnum. *See* Ex. B, McCoy Dep. at 60:7-61:10. Accordingly, Ms. McCoy had no knowledge regarding manufacturer of the implant Dr. Brassard that selected for her right hip replacement surgery, nor did she question Dr. Brassard's selection. *See id.* at 62:9-12. Thus, there is no evidence to indicate that she personally would have requested a different device if Biomet had provided different warnings directly to her.

cases only as persuasive "guidance" in determining what is contemplated by the foreseeability requirement in negligent failure to warn case).

In a negligence action – as with all product liability actions – Plaintiff must prove the existence of a defect. *Heckman v. Ryder Truck Rental, Inc.*, 962 F. Supp. 2d 792, 802 (D. Md. 2013) ("[t]he elements of proof are the same whether the claim is characterized as one for strict liability or negligence."); *see also Mohammad*, 947 A.2d at 605 (stating that the elements of a product liability claim are "(1) the *existence of a defect*; (2) the attribution of the defect to the seller; and (3) the causal relation between the defect and the injury"). Maryland courts, however, recognize only three generally accepted types of product defects: design, manufacture, and information. *See Hartford Cas. Ins. Co. v. Marpac Corp.*, 193 F. Supp. 2d 859, 862 (D. Md. 2002).

Negligence claims, moreover, depend upon the existence of a legally recognized duty. *See e.g. Gourdine*, 955 A.2d at 779. Maryland law is clear on this issue – a manufacturer has a duty to (1) design and manufacture a product is that it is safe for all reasonably foreseeable uses, *Parker v. Allentown, Inc.*, 891 F. Supp. 2d 773, 780 (D. Md. 2012), and (2) warn of reasonably foreseeable latent dangers of the product. *Moran*, 332 A.2d at 17. Plaintiffs do not limit their general negligence claim to these cognizable duties. Rather, they list multiple additional duties not supported by the law. (Compl. ¶ 111).

Plaintiffs' general negligence claim fails as a matter of law. Maryland law does not support claims based on conduct outside the scope of negligent design, manufacture, and failure to warn. Further, their cognizable claims for negligent design, manufacturing, and warning fail for the reasons demonstrated throughout this memorandum.

E. Plaintiffs' claims for breaches of implied warranties of merchantability and for fitness for a particular purpose fail because they did not give Biomet notice.

A warranty of merchantability is implied in the sale of goods if the seller is a merchant with respect to goods of that kind. Md. Code Ann., Com. Law § 2-314(1). A warranty of fitness for a particular purpose is implied in the sale of goods when "the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods." Md. Code Ann., Com. Law § 2-315. To recover for breach of either warranty, Maryland law requires a plaintiff to prove a product defect. *Ford Motor Co. v. General Acc. Ins. Co.*, 779 A.2d 362, 369 (Md. 2001). Additionally, Maryland law requires a plaintiff to give notice to the seller as a precondition to recovery. Md. Code Ann., Com. Law § 2-714(1).

Proper notice "require[s] the buyer to inform the seller of the breach, the particular goods that have been impaired, and set forth the nature of the nonconformity." *Doll v. Ford Motor Co.*, 814 F. Supp. 2d 526, 542 (D. Md. 2011). A plaintiff-buyer will be barred from recovery if he does not notify the seller within a reasonable time after he discovers or should have discovered any breach. Md. Code, Com. Law § 2-607(3)(a); *see Doll*, 814 F. Supp. 2d at 542 (explaining "[t]he Uniform Commercial Code adopted in Maryland requires a buyer to give notice to the seller for a breach of implied warranty"); *Frericks v. Gen Motors Corp.*, 363 A.2d 460, 463 (Md. 1976) ("It is clear that in an action by a buyer against his seller for a breach of warranty, the buyer must notify the seller of the alleged breach.").

As previously discussed, Plaintiffs cannot prove any alleged defect caused Ms. McCoy's injuries. Therefore, their warranty claims – like all of their claims – fail for lack of medical causation. But Plaintiffs' implied warranty claims also fail as a matter of law because they did not give notice to Biomet of any alleged breach. Ms. McCoy's first revision surgery occurred on

May 10, 2010. Ex. A, McCoy Medical Records, at UMH 936. At no point after the first or second revision surgeries did Plaintiffs contact Biomet much less give Biomet timely "notice." Biomet first learned of Plaintiffs' claims from the service of the May 11, 2012 Complaint. *See* Doc No. 1, Complaint and Jury Demand. Plaintiffs cannot prove the notice element of their alleged warranty claims and Biomet is entitled to summary judgment.

F. Biomet did not make any express warranties to Plaintiffs.

Plaintiff's breach of express warranty claim (Count IV) should be dismissed as a matter of law because Biomet never made any express warranties to Plaintiffs. A seller can create an express warranty in any of the following ways:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation.
>
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
>
> (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

Md. Code Ann., Com. Law § 2-313(1). To prevail on a breach of express warranty claim, a plaintiff must show (1) the defendant created an express warranty; (2) the product did not conform to the warranty; and (3) the lack of conformity proximately caused the injury suffered. *See Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 420 (D. Md. 2001).

Here, Plaintiffs have not established defect nor have they identified any specific statement – affirmation, promise, description, sample, or model – that formed the basis of the bargain for selecting the M2a Magnum. In fact, Ms. McCoy testified that she did not personally select the M2a Magnum device for use in her right total hip arthroplasty. Ex. B, McCoy Dep. 60:7-18. Further, Ms. McCoy testified she had never seen any marketing materials or other brochures from Biomet before she made her decision to have right hip implant surgery:

Q. Did you ever see from Dr. Brassard or otherwise any marketing materials from Biomet about your implant?
A. I cannot recall any.
Q. Do you recall Dr. Brassard giving you any brochures about the type of implant that he planned on using?
A. No, I do not recall.
Q. Did you have any discussions with anyone at Biomet before your implant surgery?
A. No.

Ex. B, McCoy Dep. 62:13-23. Ms. McCoy relied on Dr. Brassard to select the device used in her right hip replacement surgery. Ex. B, McCoy Dep. 60:13-18. Ms. McCoy did not select the device based on any alleged representations made by Biomet, so Biomet's information could not have formed the basis of the bargain for the use of the M2a Magnum in Ms. McCoy's surgery.

Similarly, Dr. Brassard testified he did not select the M2a Magnum based on marketing materials or specific information from Biomet. Ex. C, Brassard Dep. 52:3-6. Most significantly, Dr. Brassard denied he selected the M2a Magnum based on anything he was told or heard from distributors or sales representatives. Ex. C, Brassard Dep. 52:7-11. Plaintiffs' breach of express warranty claim (Count IV), should be dismissed as a matter of law.

G. Plaintiffs cannot establish that Biomet acted with actual malice to support their request for punitive damages.

Plaintiffs' request for an award of punitive damages (Count VI) should be dismissed as a matter of law for two reasons. First, to the extent that Plaintiffs' underlying product liability claims fail, those claims cannot support a claim for punitive damages. It is well settled that there can be no recovery for punitive damages unless actual and substantial compensatory damages are first shown. *See People Helpers Found., Inc. v. City of Richmond, Va.*, 12 F.3d 1321, 1327 (4th Cir. 1993) ("A majority of the fifty states prohibit punitive damages awards when a fact finder fails to award compensatory damages . . . To hold otherwise would create a windfall by allowing the recovery of damages when no actionable harm has been suffered."); *Shell Oil Co. v. Parker*, 291

A.2d 64, 71 (Md. 1972) (explaining Maryland follows the majority rule). Because Plaintiffs' substantive product liability claims fail as a matter of law, Plaintiffs' request for punitive damages likewise fails as a matter of law.

Second, even if the Court were to find that one or more of Plaintiffs' product liability claims survive summary judgment, Biomet is still entitled to summary judgment with respect to punitive damages because Plaintiffs cannot, as a matter of law, meet the high standard for punitive damages. Punitive damages may only be awarded in a non-intentional tort action where "the plaintiff has established that the defendant's conduct was characterized by evil motive, intent to injure, ill will, or fraud, *i.e.*, 'actual malice.'" *Owens-Illinois, Inc. v. Zenobia*, 601 A.2d 633, 652-53 (Md. 1992). "[I]n order for actual malice to be found in a products liability case . . . the plaintiff must prove (1) actual knowledge of the defect on the part of the defendant, and (2) the defendant's conscious or deliberate disregard of the foreseeable harm resulting from the defect." *Owens-Illinois, Inc.*, 601 A.2d at 653-55 (explaining further that "the evidence must show malicious conduct and not simply the supplying of a defective product"); *see Jeffries*, 2017 WL 2645723, at *6 (dismissing plaintiff's claim for punitive damages against IVC filter manufacturer after plaintiff did not prove manufacturer had actual malice). Further, Plaintiffs have the burden of proving punitive damages by clear and convincing evidence. *See Owens-Illinois, Inc.*, 601 A.2d at 657 (holding a "heightened standard is appropriate in the assessment of punitive damages because of their penal nature and potential for debilitating harm"). Clear and convincing evidence has "such weight that it produces in the mind of the trier of fact a firm belief or conviction, without hesitancy, as to the truth of the allegations sought to be established, and, as well, as evidence that proves the facts at issue to be highly probable." *Jimenez v. DaimlerChrysler Corp.*, 269 F.3d 439, 450 (4th Cir. 2001) (quotations and citations omitted).

Plaintiffs cannot meet these standards and certainly cannot do so by clear and convincing evidence. There is no evidence that Biomet had actual knowledge of a product defect with Ms. McCoy's M2a Magnum and of the danger of the product at the time the product left its possession or control. Furthermore, there is no evidence that armed with actual knowledge, Biomet consciously or deliberately disregarded the potential harm to consumers. On the facts of this case and the record evidence, Plaintiff cannot meet the standard for punitive damages.[11]

H. Plaintiff Kenneth Burgwin's derivative loss of consortium claim fails with his spouse's claims.

A loss of consortium claim "arises from the loss of society, affection, assistance, and conjugal fellowship suffered by the marital unit as a result of the physical injury to one spouse through the tortious conduct of a third party." *Oaks v. Connors*, 660 A.2d 423, 428 (Md. Ct. App. 1995). A claim for loss of consortium, however, is wholly "derivative" of the injured spouse's claim for personal injury. *Id.* at 430. The plaintiff must therefore prove that the defendant caused the original injury that made the other spouse suffer. "Because the loss of consortium claim is derivative of [plaintiff's] claims, it survives to the extent that the other claims survive." *McCormick v. Medtronic, Inc.*, 101 A.3d 467, 527 n19 (Md. Ct. Spec. App. 2014). Here, Plaintiffs cannot establish that Biomet is liable to Ms. McCoy for any injuries allegedly attributable to her M2a Magnum. Therefore, Mr. Burgwin's derivative loss of consortium claim necessarily fails.

V. CONCLUSION

There is no genuine dispute as to any material fact and Biomet is entitled to judgment as a matter of law. For all the foregoing reasons, Biomet respectfully urges the Court to enter summary judgment in its favor on all of Plaintiffs' claims.

[11] Biomet reserves the right to move to bifurcate punitive damages from the trial of compensatory damages if the Court declines to grant summary judgment on punitive damages. *See* Fed. R. Civ. P. 42(b).

Respectfully submitted,

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Dated: August 10, 2020

/s/ James A. Frederick

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on August 10, 2020, a copy of the foregoing **Defendants' Memorandum of Law in Support of Their Motion For Summary Judgment.** was filed and served on all counsel of record electronically via the Court's CM/ECF system.

/s/James A. Frederick
James A. Frederick